DEC 7 2005

Section 11 510(k) Device Summary

CANTERBURY

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K053031

Submitter	Canterbury Scientific Ltd 14 Pope Street Christchurch New Zealand Phone +64 3 343 3345 FAX +64 3 343 3342
Contact Person	Maurice Owen, PhD, Scientific Director
Date of Preparation	October 4, 2005
Device Name	Hemoglobin FASC Variant Control
Proprietary Name	extendSURE™ HbFASC Control
Common Name	Hemoglobin FASC Variant Control
Classification	21CFR 862.1660 Quality Control Material (assayed and unassayed)
Class	II
Product Code	JCM
Equivalent Device	Helena Laboratories, AFSC Hemo Control. (510(k) # K933086) Canterbury Health Laboratories, Hemoglobin F & A2 Control (510(k) # K011389)
Description of Device	The Hemoglobin FASC Variant Control kit contains HbA, HbF, HbS and HbC. It contains stabilizers and preservatives to maintain the stability of the hemoglobin variants. The product is provided in a lyophilized form and is reconstituted with 1.0 mL of reconstitution fluid (0.09% sodium azide) prior to use.
Intended Use of Device	The control is intended as a position marker for hemoglobin variant analysis methods such as ion exchange HPLC, capillary electrophoresis, cellulose acetate and agar/agarose gel electrophoresis. The Hemoglobin FASC control will assist in defining the elution time on HPLC or capillary electrophoresis or migration distance on electrophoresis. In this way the common hemoglobin variants can be identified and rare variants that

elute close to these can be distinguished for further characterization.

The control is for *in vitro* diagnostic use only and should not be used past the expiry date.

Comparison with Predicate Device

The device (Hemoglobin FASC Variant Control) claims substantial equivalence to device K933086 (AFSC Hemo Control) in terms of analyte composition and intended uses as a qualitative marker of variant hemoglobins to assist in identifying an unknown hemoglobin band or peak.

Substantial equivalence is also claimed to device K011389 (Hemoglobin F & A2 Control) as it is intended to be primarily used on HPLC instruments although suitable for use on electrophoresis systems. Further its form as a lyophilized product and with the same composition of stabilizers and preservatives give enhanced open vial (reconstituted) stability.

Performance Characteristics

Stability studies at 2° to 8°C were performed on the BioRad Variant with the β-thalassemia short program. The results support a shelf life (closed vial) at 2° to 8°C of 36 months from manufacture and an open vial (reconstituted) claim of 6 weeks at 2° to 8°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 7 2005

Maurice Owen, Ph.D., FACB
Scientific Director
Canterbury Scientific Limited
14 Pope Street
Christchurch 8001
NEW ZEALAND

Re: k053031
Trade/Device Name: Hemoglobin FASC Variant Control
Regulation Number: 21 CFR § 864.7415
Regulation Name: Abnormal Hemoglobin Assay
Regulatory Class: II
Product Code: JCM
Dated: October 25, 2005
Received: October 27, 2005

Dear Dr. Owen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053031

Device Name: Hemoglobin FASC Variant Control

Indications for Use:

The Hemoglobin FASC Variant Control kit contains HbA, HbF, HbS and HbC. The control is intended as a position marker for hemoglobin variant analysis methods such as ion exchange HPLC, capillary electrophoresis, cellulose acetate and agar/agarose gel electrophoresis. The Hemoglobin FASC control will assist in defining the elution time on HPLC or capillary electrophoresis or migration distance on electrophoresis. In this way the common hemoglobin variants can be identified and rare variants that elute close to these can be distinguished for further characterization.

The control is for *in vitro* diagnostic use only and should not be used past the expiry date.

Prescription Use √ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K053031